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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,478	04/21/2004	Baldomero M. Olivera	2314-280	6171

6449 7590 07/28/2006

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,478	OLIVERA ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 9-26, drawn to conotoxin propeptides and peptides, and their use in pharmaceutical methods, classified in class 514, subclass 2.

II. Claims 7-8 drawn to nucleic acids encoding conotoxins, classified in class 536, subclass 23.5.

III Claims 27-28, drawn to a method of determining a pore occlusion site on a sodium channel , classified in class 435, subclass 7.2.

IV. Claims 29-40, drawn to a method of screening a small molecule library , classified in class 435, subclass 7.1 .

V. Claims 41-42, drawn to methods of identifying therapeutic mimetics of the peptides of Group I, classified in class 424, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different functions. The primary structure of a peptide is entirely different from that of a nucleic acid. Although a polynucleotide can encode a protein, the protein can be obtained without use of a purified polynucleotide-it can be purified from natural sources or made by chemical synthesis, such as in the Merrifield procedure.

Inventions I and each of III, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide can be used, as claimed in a pharmaceutical method to alleviate physical problems associated with potassium channel regulation.

Inventions II and each of III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation. A purified nucleic acid has no role in processes using proteins.

Each of III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different functions: The invention of Group III is to determine a site on a sodium channel; the invention of group IV is to screen a small molecule library by determining binding affinity to a sodium channel, and the invention of Group V is to determine mimetics of a therapeutic activity of a conotoxin.

Should Group I or any of III-V be elected, further restriction is necessary:

This application contains claims directed to the following patentably distinct compounds, (which have different primary structures) of the claimed invention: specific peptides of SEQ ID NO:2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21,23-24, 26-27, 29-30, 32-33, 35-36, 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, 83-84, 86-87, 89-90, 92-93, 95-96, 98-99, 101-103, 105-106, 108-109, 111-112, 114-115, 117-

118, 120-121, 123-124, 126-127, 129-130, 132-133, 135-136, 138- 139, 141-142, 144-145, 147-150, 152-153, 155-156, 158-159, 161-162, 164-166, 168-173, 175- 176, 178-179, 181-182, 184-187, 189-190, 192-193, 195-196, 198-199, 201-202, 204-205, 207-208, 210-211, 213-214, 216- 217, 219-220, 222-223, 225-226, 228-229, 231-232, 234-235, 237-238, 240-241, 243-244, 246-247, 249-250, 252-253, 255-256, 258-260, 262-263, 265-266, 268-269, 271-272, 274-275, 277-278, 280-281, 283-286, 288-289, 291-292, 294-295, 297-298, 300-301, 303-304, 306-307, 309-310, 312-313, 315-316, 318-319, 321-322, 324-325, 327-328, 330-331, 333-334, 336-337, 339-340, 342-343. 345-346, 348-349, 351-352, 354-355, 357-358, 360-361, 363-364, 366-367, 369-370, 372-376, 375-376, 378-379, and 381-520. Applicant is required under 35 U.S.C. 121 to elect a single disclosed compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner will examine an identified protoxin along with the mature form. Currently, all claims of Groups I and III-V(1-6 and 9-42) are generic.

Also, should Group II be elected, further restriction is required:

This application contains claims directed to the following patentably distinct compounds, (which have different primary structures) of the claimed invention: specific nucleotide sequences encoding SEQ ID NO: 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40, 43, 46, 49, 52, 55, 58, 61, 64, 67, 70, 73, 76, 79, 82, 85, 88, 91, 94, 97, 100, 104, 109, 110, 113, 116, 119, 122, 125, 128, 131, 134, 137, 140, 143,146, 151, 154, 157, 160, 163, 167, 174, 177, 180, 183, 188, 191, 194, 197, 200, 203, 206, 209, 212, 215, 218, 221, 224, 227, 230, 233, 236, 239, 242, 245, 248, 251, 254, 257, 261, 264, 267, 270, 273, 276, 279, 282, 287, 290, 293, 296, 299, 302, 305, 308, 311, 314, 317, 320, 323, 326, 329, 332, 335, 338, 341, 344, 347, 350, 353, 356, 359, 362, 365, 368, 371, 374, 377 and 380. Applicant is required under 35 U.S.C. 121 to elect a single

disclosed compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7-8 are generic.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown by their different classifications.

Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each polypeptide and each polynucleotide sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these polypeptides and each of these polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even <u>two</u> different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, restriction for examination purposes as indicated is proper, because the search required for Group I is not required for Group II.

Applicant is advised that a reply to this requirement must include an identification of the peptide or nucleic acid that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election

This election requirement is not be construed as a species election, as these compounds do not share a common primary structure and appear to be patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-07-20

Rosanne Kosson

MARYAM MONSHIPOURI, PH.D
PRIMARY EXAMINER